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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/00, B29C 41/00, 41/08, A61M 25/10, 29/02 — A1

(11) International Publication Number: **WO 98/48879**

(43) International Publication Date: 5 November 1998 (05.11.98)

(21) International Application Number: PCT/US98/08353

(22) International Filing Date: 27 April 1998 (27.04.98)

(30) Priority Data:
08/848,592 28 April 1997 (28.04.97) US

(71) Applicant: ADVANCED CARDIOVASCULAR SYSTEMS, INC. [US/US]; 3200 Lakeside Drive, P.O. Box 58167, Santa Clara, CA 95052–8167 (US).

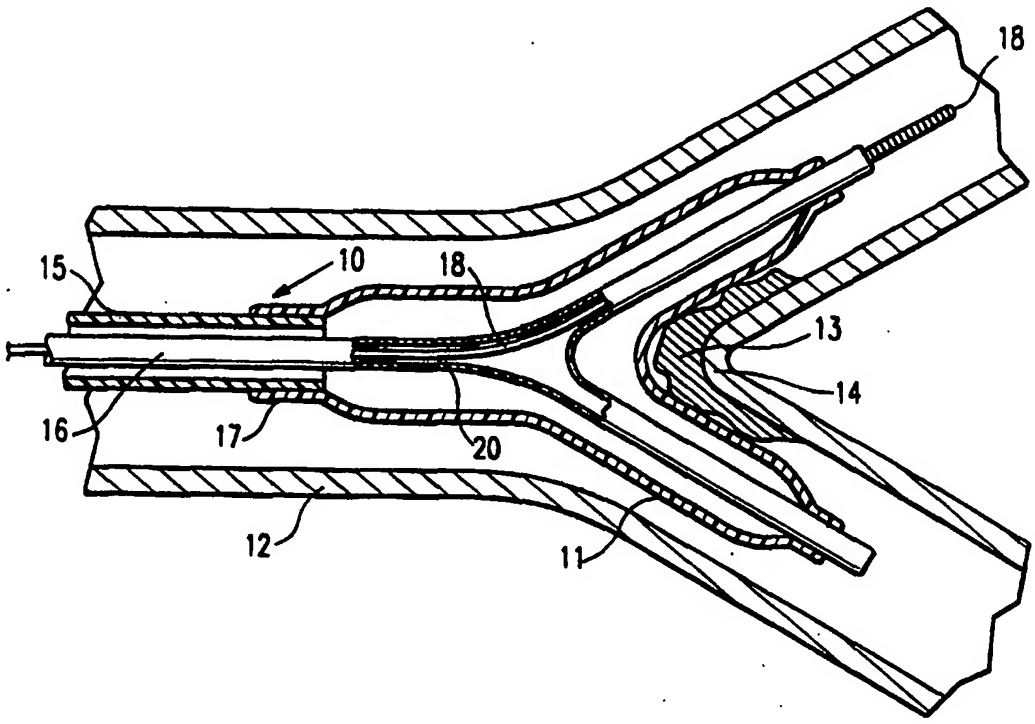
(72) Inventor: YAN, John, Yeu, Jiun; 128 Anne Way, Los Gatos, CA 95032 (US).

(74) Agents: LYNCH, Edward, J.; Heller, Ehrman, White & McAuliffe, 525 University Avenue, Palo Alto, CA 94301–1900 (US) et al.

(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: BALLOON FORMATION BY VACUUM DEPOSITION



(57) Abstract

The invention is directed to an inflatable member for intralumenal catheter which as been formed by vapor and/or gas cover deposition and a balloon formed by the method. Multi–furcated inflatable members can be made with essentially no pin holes and other defects.

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BALLOON FORMATION BY VACUUM DEPOSITION

BACKGROUND OF THE INVENTION

This invention is directed to the formation of inflatable members and particularly to inflatable balloons for dilatation catheters used in angioplasty procedures, commonly referred to as percutaneous transluminal coronary angioplasty (PTCA).

In a typical PTCA procedure a dilatation balloon catheter is advanced over a guidewire to a desired location within the patient's coronary anatomy where the balloon of the dilatation catheter is properly positioned within the stenosis to be dilated. The balloon is then inflated to a predetermined size with radiopaque liquid at relatively high pressures which can generally range from 4-20 atmospheres to dilate the stenosed region of the diseased artery. One or more inflations may be needed to effectively dilate the stenosis. The catheter may then be withdrawn from the stenosis or advanced further into the patient's coronary anatomy to dilate additional stenoses.

The catheters used to insert stents into a patient's blood vessel are very similar to the catheters employed for angioplasty. The stent is mounted onto the balloon of the catheter in a contracted or otherwise unexpanded state, the catheter with the stent is advanced through the patient's vasculature until the balloon and stent thereon are disposed within a desired region of the patient's vasculature, such as a coronary artery. The balloon is inflated to expand the stent into position within the desired region of the patient's blood vessel.

Presently used balloons are formed of a polymer such as polyethylene terephthalate (PET), polyethylene (PE), nylon and the like. The strength requirements for balloons whether for dilatation and stent delivery has tended to increase over the years. But it has become more difficult with conventional manufacturing procedures to form high strength balloons with thin walls of uniform thicknesses without pin holes. Typical procedures involve blowing of a tubular parison, usually within a mold having an interior surface corresponding to the desired inflated shape of the balloon.

Dilatation balloons of non-standard shapes, such as bifurcated balloons shown in U.S. Patent No. 4,456,000, are difficult to manufacture without seams, flow lines, flash or other defects. What has been needed and heretofore unavailable is a method of forming balloons having high strength, thin walls and low incidence of pin holes and in a variety of shapes and sizes without the prior defects. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The present invention is directed to a method of forming a thin walled high strength balloon for dilatation, stent delivery and implacement and the like, which has little incidence of pin holes and which is without seams, flow lines, flash or other defects.

In one presently preferred embodiment of the invention, a balloon is formed by deposition of a thermoplastic polymeric material or thermoplastic elastomeric material onto a mandrel of desired shape in a vacuum or low pressure environment and preferably under cover of an inert or non-reactive gas such as argon, nitrogen and the like. The mandrel has an exterior shape which corresponds to the desired inflated shape of the balloon. One presently preferred method of depositing the polymeric material onto the mandrel is radio frequency (RF) sputtering. Another method is plasma coating. Other vacuum or vapor deposition methods may also be employed to deposit polymeric material onto a mandrel to form a balloon. Suitable polymeric materials which may be vacuum deposited onto a mandrel to form a balloon include conventional dilatation balloon materials such as polyethylene, polyvinyl chloride, polyethylene terephthalate, nylon and other polyamides and zinc and sodium ionomers (e.g. Surlyn). Balloons formed of other less conventional materials such as polypropylene, polyimide, various fluoropolymers and proprietary polymeric materials such as Parylene and Parylast which are available from Advanced Surface Technology, Inc. of Billerica, Mass., may also be made with the method of the invention. Blends of polymeric materials are also suitable for deposition. Composite balloons and other catheter parts with separate layers of different polymeric materials may also be formed by the vacuum deposition of the polymeric materials. For example, a first component such as a balloon can be

formed in the manner of the invention, and then be assembled with a suitable inner tubular member and catheter shaft. After the assembly, the balloon can be first coated in the manner of the invention with a suitable material such as Parylene and then Parylast is applied to further secure the balloon to the catheter shaft.

Generally, the vacuum deposition is conducted within a chamber that has a vacuum level of about 10^{-2} to about 10^{-10} torr, preferably about 10^{-3} to about 10^{-6} Torr. The gas cover is preferably argon for RF sputtering and nitrogen for plasma deposition. Other relatively inert or otherwise non-reactive gases may likewise be employed in this regard.

The balloon of the invention can be formed with a wall thickness which is uniform and accurate. Wall thicknesses between about 0.3 to over 2 mils (0.008-0.05 mm) and typically from 0.5 to about 1.5 mils (0.013-0.038 mm) can be readily formed with variations from 0.05 to 0.3 mils (0.0013-0.008 mm), typically about 0.1 to about 0.2 mils (0.0025-0.005 mm). Moreover, the balloon is essentially pin hole free and has no seams, flow lines, flash or other defects. The method of the invention is particularly adaptable to the manufacture of balloon shapes other than conventional cylindrical working sections with tapered ends, e.g. multi-furcated balloons, i.e. balloons with multiple distal portions which extend distally a angles from one another. These and other advantages of the invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a longitudinal cross-sectional view of a dilatation catheter with a bifurcated balloon structure within a patient's blood vessel position to dilate an accumulation of plaque at an arterial branch.

Fig. 2 is a perspective of the bifurcated balloon shown on the catheter depicted in Fig. 1.

Fig. 3 is an elevational view, partially in section, of a bifurcated mandrel with a bifurcated balloon deposited thereon in accordance with the present invention.

Fig. 4 is a schematic view of a system for the vacuum deposition of a polymeric layer onto a suspended mandrel to form a bifurcated balloon by RF sputtering.

Fig. 5 is a schematic view of a system for the vacuum deposition of a polymer material onto a suspended mandrel to form a bifurcated balloon by plasma deposition.

DETAILED DESCRIPTION OF THE INVENTION

Reference is made to Fig. 1 which illustrates the distal portion of a dilatation catheter 10 having a bifurcated balloon 11 within a forked branching of a patient's coronary artery 12 for dilating plaque 13 at the branch point 14 of the artery. The catheter 10 has an outer tubular member 15, a Y-shaped inner tubular member 16, a bifurcated balloon 11 having a proximal end 17 secured to the distal end of the outer tubular member 15 and distal ends of each of the bifurcated portions secured to the distal ends of the Y-shaped inner tubular member. A guidewire 18 is slidably disposed within the inner lumen 20 which extends within the inner tubular member 16.

The bifurcated balloon 11 is best illustrated in the perspective view shown in Fig. 2. Fig. 3 illustrates a bifurcated mandrel 21 onto which a layer 22 of polymeric material has been vacuum deposited to form the bifurcated balloon 11 as shown in Fig. 2.

Fig. 4 illustrates a system for depositing a polymer film 22 onto a bifurcated mandrel 21 as shown in Fig. 3. This system includes a vacuum chamber 23 in which the mandrel 21 is suspended. A body 25 of target material, e.g. polyethylene, is suspended within the vacuum chamber 23 and is electrically connected to a RF source 26 through cable 27. A suitable pump 28 is connected to the vacuum chamber 23 through conduit 29 to develop a vacuum within the chamber 24 at the desired levels. A source 30 of inert or non-reactive gas, e.g. argon or nitrogen, is likewise connected to the vacuum chamber 23 through a conduit 31. A vent line 32 is provided with a valve 33 to vent the chamber 23 at the end of the process.

The system shown in Fig. 4 is operated in the following manner. The mandrel 21 is suspended within the chamber 23 and the body 25 of target material is

supported within the chamber electrically connected by cable 27 to an RF electrical energy source 26. The chamber 23 is closed and the pump 28 is actuated to develop a vacuum within the chamber of about 10^{-7} torr. An inert gas, in this case argon, is injected into the chamber 23 from the source 30 to serve as the bombardment source. After stabilization of the vacuum within the chamber 23 at a desired level of about 10^{-4} torr, the RF power is turned on. A plasma is generated within the chamber 23 between the polyethylene body 25 and the mandrel 21 by the ionized argon gas which bombards the polyethylene body causing dislocation of atoms and molecules of target material from the surface of the polyethylene body and the deposition thereof onto the surface of the mandrel 21. On the surface of the mandrel 21, the deposited material reacts to form a polymeric film similar to the original target material. When the desired film thickness is reached, the power to the RF source 26 is turned off. The vacuum chamber 23 is then vented through conduit 32 by opening the valve 33. When the chamber reaches atmospheric pressure, the chamber is opened and the coated mandrel 21 is removed. The mandrel 21 may be separated from the bifurcated balloon 11 formed on the surface thereof by a variety of means. For example the mandrel 21 may be made of material which is easily dissolvable by a suitable solvent which does not effect the polymeric layer on the mandrel. The proximal and distal ends of the balloon 11 are clipped to a desired length and the balloon then assembled onto the catheter shaft in a conventional manner. The balloon has a uniform thickness and no pinholes seams, flow lines, flash or other defects.

Fig. 5 illustrates an alternative system for depositing a polymer film 22 onto a bifurcated mandrel 21 as shown in Fig. 3. This system includes a vacuum chamber 34 in which the mandrel 21 is suspended. A suitable pump 35 is connected to the vacuum chamber 34 through conduit 36 to develop a vacuum within the chamber 34 at the desired levels. A vent line 37 is provided with a valve 38 to vent the chamber 34 at the end of the process. A vaporizing vessel 41 is filled with an appropriate amount of dichloro-p-xylylene dimer. A pyrolyzer vessel 42, in fluid communication with the vaporizing vessel 41 through conduit 43, is heated to a temperature of about 700° C. When the temperature of the pyrolyzer vessel 42 is stabilized, the dimer in the vaporizer 41 is vaporized by heating the dimer to 200° C. Valve 44 in

the conduit 43 is opened allowing the vaporized dimer to flow into the pyrolyzer vessel, where the dichloro-p-xylylene is heated and then into the pyrolyzer chamber 45 through conduit 46, where the dichloro-p-xylylene is cleaved into two reactive monomeric species of monochloro-p-xylylene. The reactive monomers are directed through conduit 47 to the vacuum chamber 34 which has been pumped down to a desired vacuum level of about 10^{-4} torr by pump 36. Within the vacuum chamber 34 the monomers polymerized at room temperature as a film of Parylene C on the surface of the mandrel 21 disposed in the chamber. When the desired polymer thickness is formed on the mandrel surface, e.g. when a fixed amount of the dimer source is depleted from the vaporizer, the vacuum chamber is vented through line 37 by opening valve 38 as in the previous example and the vacuum chamber opened so that the coated mandrel 21 can be removed. Once removed from the vacuum chamber 34, the polymer balloon 11 on the mandrel 21 can be separated in a manner as previously described.

Suitable deposition systems for the present invention include the CrC Sputtering System, particularly the CrC-150 System with a 200 watt RF power supply, available from Plasma Sciences, Inc. of Lorton, VA and Specialty Coating System's (Indianapolis, IN) Parylene Coater.

Other uses may be made of the present invention. For example, the Y-shaped inner member can be made in essentially the same manner. Other alternatives include forming a Y-shaped tubular member in the manner of the invention and then irradiating the portions of the tubes which are to be blown into balloons, and the blowing the irradiated sections in a conventional manner. The method of the invention can also be employed to apply a layer of material onto a previously formed balloon so as to reap the benefits of a composite construction. Other modifications will become apparent to those skilled in the art.

Although individual features of embodiments of the invention may be shown in some of the drawings and not in others, those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of one or more of the other embodiments. Moreover, various changes and modification can be made to the invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. A method for forming an inflatable member having an interior chamber, comprising:

a) providing a mandrel having an exterior surface which corresponds to the desired form of the interior chamber of the inflatable member;

b) depositing a thin film of polymeric material under low pressure or inert or non-reactive gas cover onto the exterior surface of the mandrel to form the inflatable member thereon; and

c) separating the inflatable member from the mandrel.

2. The method of claim 1 wherein the polymeric material is deposited by means of RF sputtering.

3. The method of claim 1 wherein the polymeric material is deposited by means of plasma deposition.

4. The method of claim 1 wherein the polymeric material is thermoplastic or thermoplastic elastomeric.

5. The method of claim 1 wherein the polymeric material is selected from the group consisting of polyethylene, polyvinyl chloride, polyethylene terephthalate, polyamides, zinc ionomers, sodium ionomers, polypropylene, polyimide and fluoropolymers.

6. An elongated inflatable member of a desired shape having an interior chamber and at least one thin walled cylindrical portion which has been formed by deposition of polymeric material onto a mandrel having the shape of the desired shape of the inflatable member.

7. The elongated inflatable member of claim 6 wherein the wall thickness is about 0.3 to about 2 mils.

8. The elongated inflatable member of claim 6 wherein the wall thickness is about 0.5 to about 1.5 mils.

9. The elongated inflatable member of claim 7 wherein the variation in wall thickness is not greater than 0.2 mils.

10. A dilatation catheter comprising :

a) an elongated shaft having proximal and distal ends, an inflation lumen extending therein;

b) a multifurcated balloon on a distal portion of the elongated shaft with each of the balloon multifurcations having an interior in fluid communication with the inflation lumen, a distal skirt and having no seams, flow lines or flash; and

c) an inner tubular member extending within the elongated shaft having multifurcated distal portions which extend through the interior of the multifurcated balloons and having distal extremities to which the distal skirts of the multifurcated balloons are secured.

11. The dilatation catheter of claim 10 wherein the multifurcated balloon is formed by deposition onto a mandrel of a desired shape.

12. The dilatation catheter of claim 11 wherein the wall thickness is about 0.5 to about 1.5 mils.

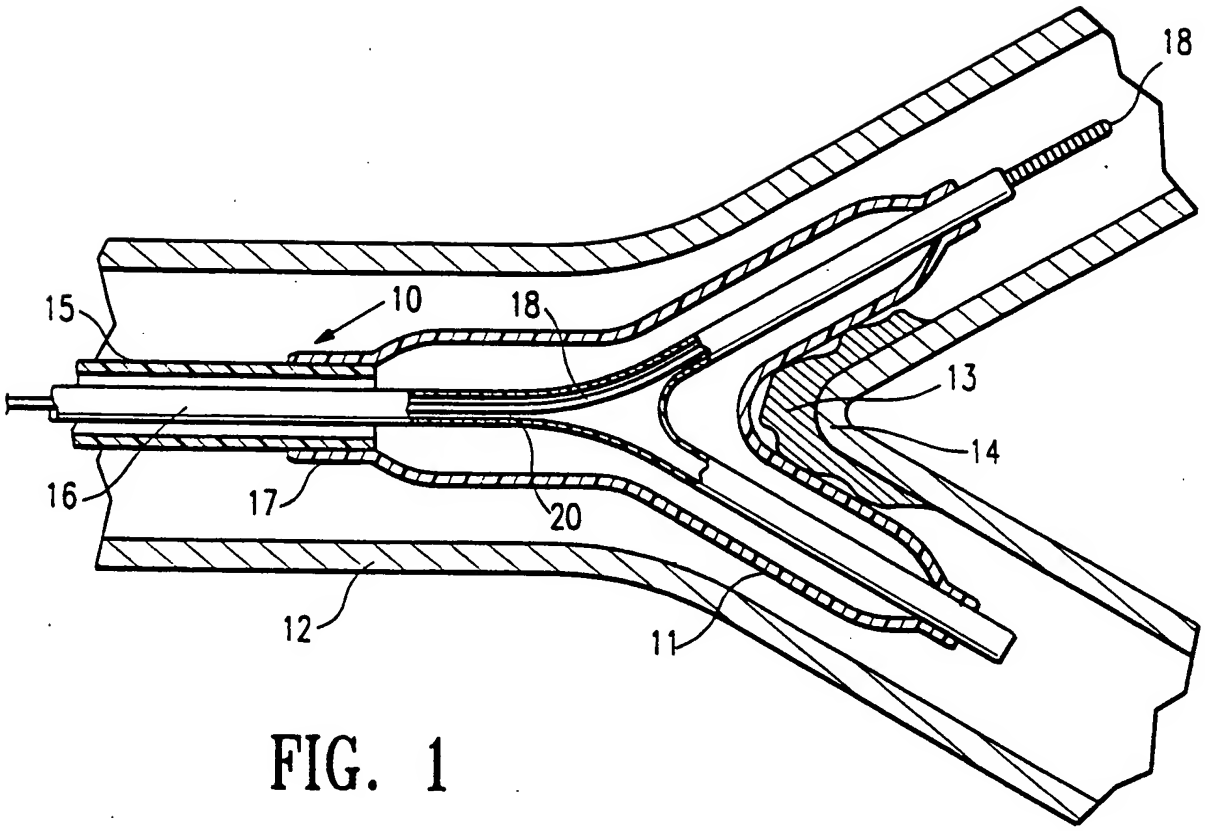

FIG. 1

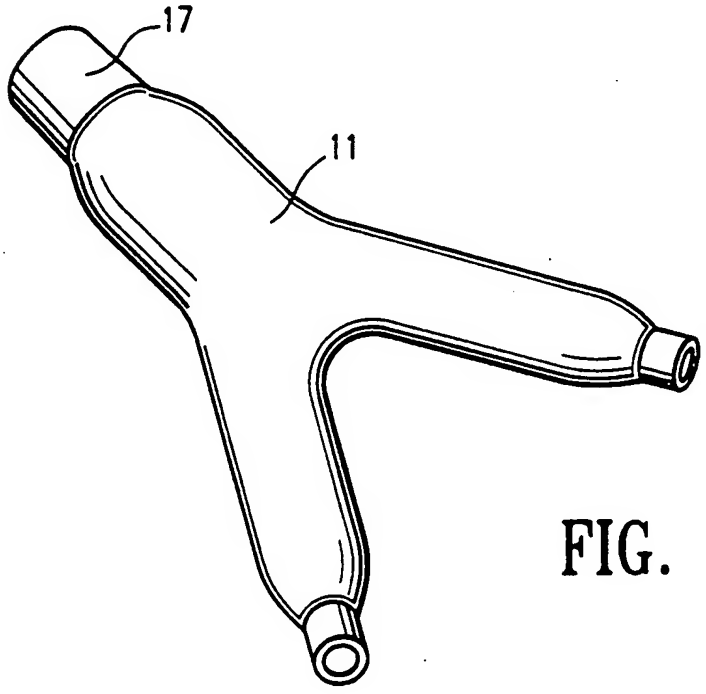

FIG. 2

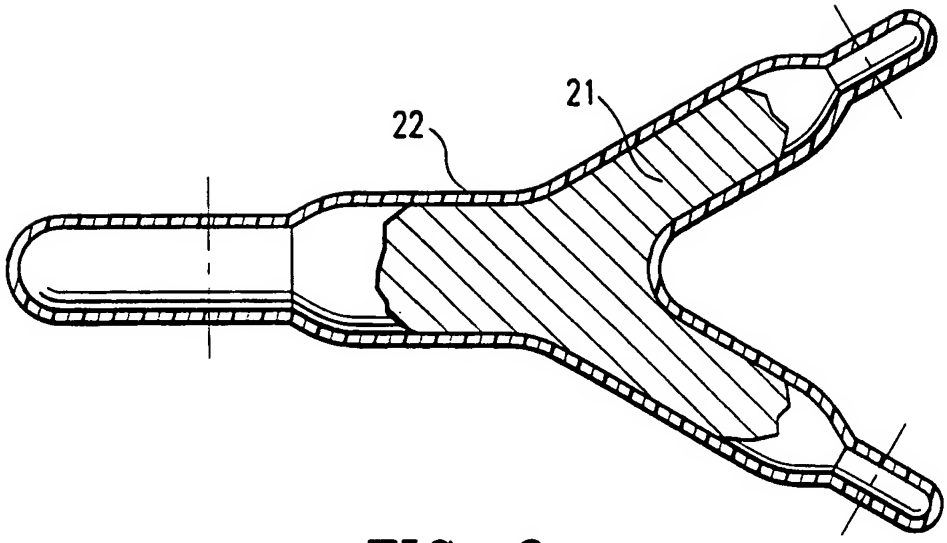
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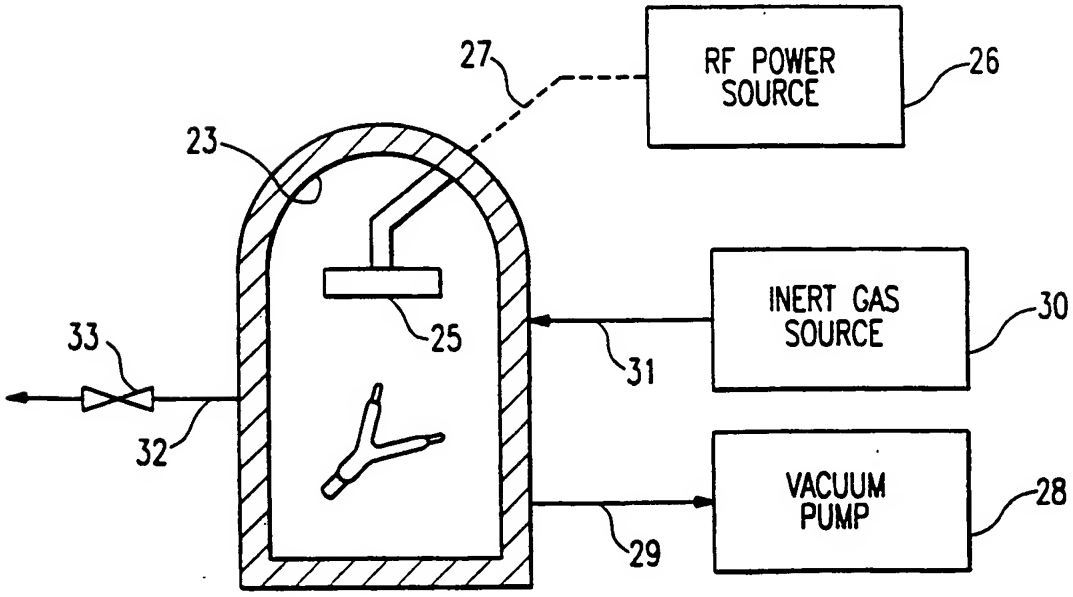
FIG. 3


27
RF POWER SOURCE
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INERT GAS SOURCE
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VACUUM PUMP
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FIG. 4

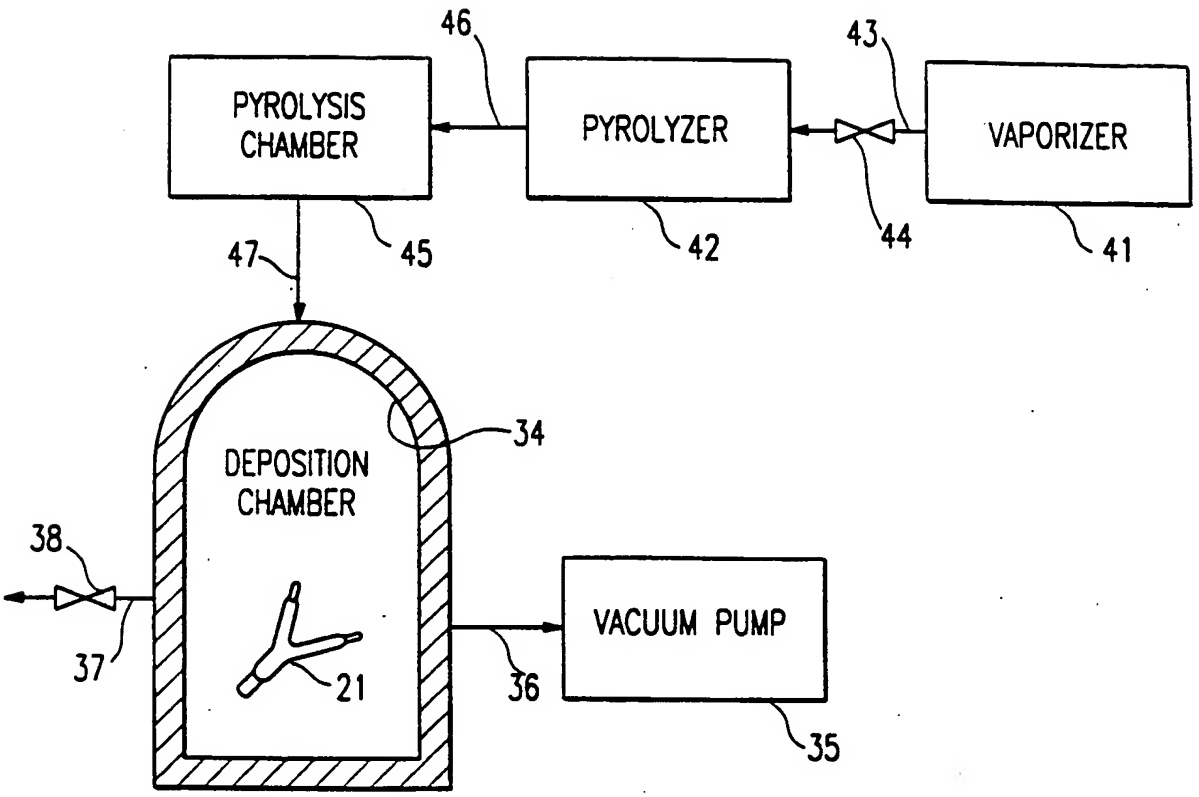
PYROLYSIS CHAMBER
PYROLYZER
VAPORIZER
DEPOSITION CHAMBER
VACUUM PUMP
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FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/08353

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00 B29C41/00 B29C41/08 A61M25/10 A61M29/02

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 952 357 A (EUTENEUER CHARLES L) 28 August 1990 see column 3, line 3 - column 4, line 27; figures 2-4	1,6
A	US 4 743 327 A (DEHAAN ABEL ET AL) 10 May 1988 see the whole document	1,6
P,X	WO 97 16217 A (DEBIOTECH SA ;MAILLARD LUC (FR)) 9 May 1997 see the whole document	10
X	US 4 994 071 A (MACGREGOR DAVID C) 19 February 1991 see column 5, line 16 - column 5, line 25; figure 3	10

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

Date of the actual completion of theinternational search	Date of mailing of the international search report
17 August 1998	24/08/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jameson, P

1

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 613 980 A (CHAUHAN TUSHARSINDHU C) 25 March 1997 see the whole document	10
A	US 4 413 989 A (SCHJELDAHL GILMORE T ET AL) 8 November 1983 see column 10, line 44 - column 11, line 39; figure 5	10
A	EP 0 347 023 A (BARD INC C R) 20 December 1989 see the whole document	10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/ 08353

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims: 1-9 Method of forming an inflatable member and the inflatable member
2. Claims: 10-12 Dilatation catheter with multifurcated ballon

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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